

## MAZIE SLATER KATZ & FREEMAN, LLC

103 Eisenhower Parkway, Suite 207, Roseland, NJ 07068

Phone: (973) 228-9898 - Fax: (973) 228-0303

[www.mazieslater.com](http://www.mazieslater.com)

David A. Mazie\*  
Adam M. Slater\*<sup>o</sup>  
Eric D. Katz\*<sup>o</sup>  
David M. Freeman  
Beth G. Baldinger  
Matthew R. Mendelsohn\*<sup>o</sup>  
David M. Estes  
Adam M. Epstein<sup>o</sup>

Karen G. Kelsen<sup>o</sup>  
Cory J. Rothbort\*<sup>o</sup>  
Michael R. Griffith<sup>o</sup>  
Christopher J. Geddis  
Samuel G. Wildman  
Julia S. Slater<sup>o</sup>

<sup>o</sup>Member of N.J. & N.Y. Bars

\*Certified by the Supreme Court of  
New Jersey as a Civil Trial Attorney

September 22, 2023

*Via ECF*

Honorable Thomas I. Vanaskie, Special Master  
Stevens & Lee, P.C.  
1500 Market Street, East Tower, 18th Floor  
Philadelphia, Pennsylvania 19103

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*,  
No. 1:19-md-02875-RBK (D.N.J.)

Dear Judge Vanaskie:

Plaintiffs respectfully submit this letter in advance of the September 26, 2023 status conference.

### **1. Losartan Discovery End Dates**

During the previous case management conference, Plaintiffs asked the Court to define the end of the Relevant Time Period for custodial discovery as the present. However, Plaintiffs agreed to a compromise, which was read into the record during the Case Management Conference on September 12. Specifically, that compromise allowed Plaintiffs to select certain custodians where the production would continue to the present, and the files of the custodians not selected would be collected through December 31, 2019.

Plaintiffs' positions as to each defendant are set forth below.

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*a. Aurobindo*

Plaintiffs still have outstanding disputes with Aurobindo on the number of custodians. The Parties have jointly agreed on a total of 22 custodians. While Plaintiffs still have a good faith basis to ask that all custodial productions continue to the present, Plaintiffs have proposed that only 13 of the 22 need to have their productions continue. This list was carefully selected based upon who would have been involved in responding to the 2022 FDA Warning Letter<sup>1</sup> sent to Aurobindo, as well as ongoing regulatory issues.

Aurobindo has agreed to only two additional custodians, Blessy Johns and Dr. Rao. While both of these individuals unquestionably will have relevant information, the production should not stop here. As the Parties learned during the first round of discovery, FDA inspections and the resulting warning letters involve large teams of people from different parts of the company. The 2022 Warning Letter, which cited Aurobindo for ongoing cGMP failures dating back to 2019, was specifically directed at Aurobindo Unit I, one of the units which manufactured Aurobindo's irbesartan API. To that end, Plaintiffs' proposal is that the custodians from Unit I, as well as those who would have been involved in the Warning Letter response at a corporate level, have their relevant time period extended to the present.

Plaintiffs have agreed to allow the custodial productions to end on December 31, 2019 for the following custodians. This first list is not subject to dispute:

<b>Custodian Name</b>	<b>Department</b>	<b>Title</b>	<b>Custodial Production Start Date</b>	<b>Custodial Production End Date</b>
Kalakada Narasimha Reddy	Manufacturing - Unit 1	Vice President of Operations	9/1/13	12/31/19

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<sup>1</sup> <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/aurobindo-pharmaceutical-limited-618091-01122022>.

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Ram Pravesh Singh	Manufacturing - Unit 9	Associate Vice President	9/1/13	12/31/19
Hanumanthu Penchalaiah	Pharmacovigilance	Senior General Manager HO-FDF	9/1/13	12/31/19
Shahid Siddiqui	Quality Assurance	General Manager - Research Centre II	9/1/13	12/31/19
Kurresambi Reddy	Quality Assurance	Head of Quality/Senior General Manager for Unit 9 Quality Assurance	9/1/13	12/31/19
Swaminathan Srinivas	Quality Assurance - Unit 9	Deputy General Manager Quality Assurance - Unit 9	9/1/13	12/31/19
Vijay Kumar Handa	R&D	President of Chemical Research	9/1/13	12/31/19
Hemant Kumar Sharma	R&D	President - Research Centre II	9/1/13	12/31/19
Rajaeev TL	Sales	US Sales	9/1/13	12/31/19

Plaintiffs believe the custodial productions should continue for the following individuals.

Aurobindo has agreed to extend the production for the two custodians highlighted in green but disputes the rest:

<b>Custodian Name</b>	<b>Department</b>	<b>Title</b>	<b>Custodial Production Start Date</b>	<b>Custodial Production End Date</b>
Govindarajan Narayanan	Head of APL	Managing Director	9/1/13	Present
Gattupalli Madhava Ramprasad	HO - API	Sr. General Manager of CMSAT	9/1/13	Present

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Srinivas K. Rama	HO - API	Associate President	9/1/13	Present
Subramanyam Maddala	HO - API	President	9/1/13	Present
Madhusudhana Reddy	Manufacturing	General Manager HO API	9/1/13	Present
A. Vannur Reddy	Quality Assurance	Deputy Manager Unit 1 QA	9/1/13	Present
R. Nagaraju	Quality Assurance	Executive , Quality Assurance	9/1/13	Present
Ram Mohan A Rao	Quality Assurance	Chief Quality Officer - Unit 3	9/1/13	Present
Sudhakar Reddy Mandepudi	Quality Assurance	President of Corporate Quality Assurance	9/1/13	Present
C.V. Satyendranath	Quality Control	Associate Vice President Corporate QC 1	9/1/13	Present
Jaipal Reddy	Quality Control	General Manager - Quality Control Unit 1	9/1/13	Present
Blessy Johns	Regulatory Affairs	Vice President of Regulatory Affairs	9/1/13	Present
Dasarathi	Regulatory Affairs	Head of Regulatory Affairs - Corporate API	9/1/13	Present

Plaintiffs' position meets Aurobindo in the middle and reflects a fair and tailored compromise to the issued that continued at Aurobindo beyond 2019. Plaintiffs therefore ask that the Court require Aurobindo to collect the custodial files of the individuals listed above through to the present time.

*b. Sciegen*

The Parties have reached an agreement that the Relevant Time Period for the following ScieGen custodians will run to the present:

- Siva Reddy

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- P. Raghuram

*c. ZHP*

The Parties have held productive meet and confer sessions and request an extension until the next discovery conference to present any remaining disputes so that meet and confers can continue.

*d. Hetero*

The Parties have reached an agreement that the following HLL custodians will be subject to an extended Relevant Time Period for the collection and production of their custodial documents to the present, subject to further confirmation of their roles and involvement:

- Ramana, Venkata M.
- Murali, N.
- Panchakshari, N.G.
- GopalKrishna, T.
- Souhassouri, J.

Additional custodians may be identified for extended collection and production as to HLL as roles and involvement are clarified through discovery. The Parties have also agreed that custodians to be identified as to Hetero USA and Camber, which were involved with regulatory, nitrosamine testing, and recall issues, will be subject to an extended Relevant Time Period for the collection and production of custodial documents to the present; however, the Parties are still in the process of determining the exact identity of those custodians.

*e. Vivimed*

The Parties previously came to an agreement on custodians. The only dispute remaining was the end of the relevant time period. The Parties have come to an agreement that six of the nine

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custodial files will be produced through December 31, 2019. Three of the remaining custodians' files will be produced through the present:

- Nagesh Majeti
- Chandran Tiruvattar
- Balu P.

*f. Teva*

Plaintiffs and Teva have reached agreement that they will search all agreed-upon custodians' files for the time period of May 1, 2010, through June 10, 2020. They also have agreed that certain custodians or non-custodial sources will be searched for responsive documents post-dating this time period. The Parties continue to negotiate which custodians or non-custodial sources will be so searched. Because it is anticipated agreement likely can be reached in this regard, Plaintiffs do not believe there is any ripe dispute to present at this time with respect to Teva.

*g. Torrent*

Torrent and Plaintiffs continue to meet and confer in good faith regarding the end date for collection of documents for Torrent custodians. To date, Torrent and Plaintiffs have reached agreement regarding the end date for collection for the following custodians:

1. Dawn Chitty
2. Bernadette Attinger
3. Saroja Garontla
4. Dhruvit Shah
5. Joshi Shubham
6. Paras Sheth
7. Kelly Gegenheimer

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8. Prajyot Kulkarni
9. Anupama Siddhaye
10. Brijesh Patel
11. Swati Panwar
12. Sanjay Barhate

The Parties are continuing to meet and confer regarding the end dates for the remaining nine custodians, and will be prepared to address outstanding disputes (if any) at the October 4, 2023 Case Management Conference.

**2. Status Updates on CMO No. 32 Discovery Regarding Wholesalers and Retail Pharmacy Defendants**

*a. Retail Pharmacy Defendants*

There is no dispute between Plaintiffs and Retail Pharmacy Defendants at this time. Last month, consistent with CMO No. 32 and the Special Master's subsequent rulings, Retailer Pharmacy Defendants produced the consumer identifier and the amounts paid by TPPs. Plaintiffs are still reviewing all of these data and will follow-up with Retailer Pharmacy Defendants as necessary about these data. Retail Pharmacy Defendants also have proposed custodians, and the Parties are negotiating potential additional custodians as well as search terms. Finally, as to the final CMO No. 32 item (costs/profits data), Retail Pharmacy Defendants will be producing data and information per the previously entered, agreed-upon schedule.

*b. Wholesaler Defendants*

To date, Wholesaler Defendants have only produced the amounts they paid for VCDs, and the amounts at which they sold VCDs downstream. They have yet to produce any data or information about their costs or profits. Wholesaler Defendants have repeatedly told Plaintiffs

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since CMO No. 32 (entered April 21, 2023), that they and their experts are working on it. Wholesaler Defendants also have yet to identify specific custodians. While there is no dispute per se, Plaintiffs are concerned that Wholesaler Defendants' pace, which is well behind that of Retail Pharmacy Defendants, may jeopardize other deadlines.

Thank you for your courtesies and consideration.

Respectfully,



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ADAM M. SLATER

cc: All Counsel (via CM/ECF)